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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/511,064      | 04/20/2005  | Scott Alan Jelinsky  | AM100877            | 8561             |

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| EXAMINER |
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LUNDGREN, JEFFREY S

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| ART UNIT | PAPER NUMBER |
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1639

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03/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |                               |                                 |  |
|---|-------------------------------|---------------------------------|--|
| <b>Advisory Action</b><br><b>Before the Filing of an Appeal Brief</b> | Application No.<br>10/511,064 | Applicant(s)<br>JELINKSY ET AL. |  |
|   | Examiner<br>Jeff Lundgren     | Art Unit<br>1639                |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 1/29/07 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-4.  
Claim(s) withdrawn from consideration: 6 and 8-59.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see continuation.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**MARK L. SHIBUYA**  
**PRIMARY EXAMINER**

**ADVISORY ACTION (continued)**

***Claim Rejections - 35 USC § 112, first paragraph - Withdrawn***

The rejection of claims 1-4 and 6, under 35 U.S.C. § 112, first paragraph, for lack of adequate written description is withdrawn in view of Applicants' amendments to the claims.

***Claim Rejections - 35 USC § 102(b) - Maintained***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4, under 35 U.S.C. 102(b) as being anticipated by Ecker *et al.*, U.S. Patent No. 5,747,253, issued on May 5, 1998, is maintained.

Claim 1 is directed to an isolated plurality of genes, wherein the plurality comprises two groups of genes, wherein each gene in the first group is differentially expressed at higher levels in kidney upon estrogen exposure, and wherein each gene in the second group is differentially expressed at lower levels in kidney cells upon estrogen exposure. It is noted that Applicants define gene in the specification as follows:

**"In general, 'a gene' is a region on the genome that is capable of being transcribed to an RNA that either has a regulatory function, a catalytic function and/or encodes a protein. A gene typically has introns and exons, which may organize to produce different RNA splice variants that encode alternative versions of a mature protein. '*Gene*' *contemplates fragments of genes that may or may not represent a functional domain.*"**

Specification, paragraph 0042 (emphasis added).

Ecker teaches the use of all possible 8-mer DNA probes (*i.e.*, gene fragments):

**"A group of 65,536 unique 8-mers in 4 sets of 16,348 was prepared in accordance with Examples 3 and 6 each was screened for activity against human herpes simplex virus type 1 (HSV-1) in cell culture in accordance with the procedure described in Example 9. As illustrated in Table 4, antiviral activity was observed with increasing potency at each round of synthesis and screening, with no difficulty discerning the most active set (in bold) in each round."**

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Ecker, see Example 13, cols. 19 and 20.

Accordingly, Ecker teaches all possible genes (*i.e.*, gene fragments), and therefore metes the limitation of an isolated plurality of “genes” comprising two groups: the first group comprising “genes” expressed at higher levels in kidney cells upon exposure to estrogen (including all 8-mers of NTT73, CYP7B1 and ABCC3), and the second group comprising “genes” expressed at lower levels in kidney cells upon exposure to estrogen (including all 8-mers of SAHH and BHMT).

Applicants’ briefly contend that:

“Amended claim 1 recites a particular plurality of genes: the combination of all of ABCC3, NTT73, and CYP7B1 as the first group and; and BHMT and SAHH, as the second group. The 8-mer DNA probes of Ecker do not teach the ABCC3, NTT73, CYP7B 1, BHMT and SAHH *genes*.”

Since Ecker fails to teach all of the elements of the amended claims, Ecker cannot anticipate the present application. Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) under Ecker be withdrawn.”

Amendment After Final Action, page 12, paragraphs 1 and 2 (emphasis added).

Applicants’ arguments have been fully considered, however, are unpersuasive because Applicants have failed to address the following: 1) how a the term “gene” as used in claim 1 does not read on an 8-mer; and 2) how a set of all possible 8-mers, such as the 8-mers disclosed in Ecker, would not have at least one sequence that would have 100% homology over an 8 nt span with each of ABCC3, NTT73, CYP7B 1, BHMT and SAHH.

The rejection is maintained.

### ***Conclusions***

No claim is allowed.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should

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Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL



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